

REMARKS/ARGUMENTS

Claims 8-13 are pending herein. Claim 13 has been amended hereby to correct matters of form only. Applicant respectfully submits that no new matter has been added. Applicant respectfully submits that this Amendment is proper under Rule 116, because changing claim 13 to properly depend from claim 11 does not create new issues, and merely places the application in better condition for appeal, if necessary. Accordingly, entry and consideration of this Amendment is respectfully requested.

A Notice of Appeal is filed herewith to preserve the pendency of this application while the PTO considers the claim change and the remarks presented herein.

1. The §112, second paragraph rejection of claim 13 is noted, but deemed moot in view of rewritten claim 13 submitted above. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

2. Claims 8, 10, 11 and 13 were rejected under §102(b) over Resmer, and claims 8-13 were rejected under §103(a) over Resmer in view of Kabushiki. Applicant respectfully traverses these rejections.

Independent claim 8 recites an enteral nutrition product for enteral administration, not orally, but directly to a stomach or intestines of a dysphagic patient from an external container connected to an external portion of a feeding tube provided through a through-hole of a stoma formed through a portion of the abdominal and stomach walls of the patient upon the application of pressure to said external container. The enteral nutrition product comprises a semi-solid material having a substantially self-supporting consistency that deforms to flow under an externally applied load without liquefying and that is capable of containing a higher concentration of a nutrient component than a liquid. The semi-solid material comprises a mixture of a liquid nutrient solution and a semi-solidifying agent comprising agar that is added to the liquid nutrient solution. The mixture comprises the semi-solidifying agent and the liquid nutrient solution in a predetermined ratio that

is sufficient to ensure that the self-supporting consistency of the semi-solid enteral nutrition product remains substantially unchanged before, during, and after enteral administration of the semi-solid enteral nutrition product into the patient. The self-supporting consistency of the semi-solid enteral nutrition product is further maintained within the stomach or the intestines of the patient such that the semi-solid enteral nutrition product does not liquefy due to the body temperature of the patient, to thereby prevent the patient from experiencing gastro-esophageal reflux.

Applicant respectfully submits that, contrary to the PTO's assertions, Resmer fails to disclose or suggest each and every feature in independent claim 8 for at least the reasons explained below.

The PTO asserted that "the [Resmer] patent meets each of the compositional limitations of the claims namely it discloses an enteral feeding tube composition comprising a nutrient liquid and a semi-solidifying agents. By meeting these limitations any composition would inherently meet the functional limitations since those limitations would fall naturally from the properties of the components" (Office Action, page 3, last 5 lines). Applicant respectfully submits that the PTO is incorrect.

Applicant respectfully submits that the PTO's position is predicated on a lack of knowledge of the actual properties of agar, and is merely based on the incorrect premise that once the concentration of agar used is specified, the functional limitation set forth in claim 8 is automatically and without exception achieved.

The alleged "functional limitations" of claim 8 describe the physical, structural characteristics of the claimed enteral nutrition product, namely the consistency of the enteral nutrition product, which depends not only on the concentration of agar contained in the product, but also on the type of agar selected. The present specification explicitly shows that agar is selected as powder agar, while Resmer does not disclose or suggest the use of powder agar. Applicant respectfully submits that one skilled in the art would readily appreciate and understand that the mere presence of some form of agar would not be expected to result in the same novel and non-obvious consistency characteristics defined in independent claim 8.

Moreover, Applicant respectfully submits that the Rule 132 Declaration submitted on April 15, 2008, includes tangible evidence of secondary considerations that concretely demonstrates the non-obviousness of the present invention. Appendix D of the Rule 132 Declaration is a medical arts trade article, co-authored by the Applicant, describing the unexpected nature of the beneficial results attributable to enteral nutrition products within the scope of the present invention.

This declaration evidence does not directly compare the present invention to the closest prior art with respect to now applied by the PTO, because that art was not applied at the time the declaration was submitted, and because such a direct comparison is not relevant with respect to the fact that the present invention has received peer recognition, commercial success and fulfills a long felt but heretofore unresolved need, even in view of the existence of that prior art. Applicant respectfully submits that the prior art tube food of Resmer is merely an example of the type of prior art having the practical problems now resolved by the present invention, and further demonstrates that the present invention offers a significant and non-obvious improvement over seemingly, but patentably distinct prior art, including Resmer.

In addition, Applicant respectfully submits that the formulation of the enteral nutrition product according to the article in Appendix D of the Declaration is within the scope of claim 8, and provides further evidence that the unexpected results attributable to the broadest independent claim are found to be common among specific embodiments that fall within the scope of claim 8.

Applicant respectfully submits that the combination of Resmer and Kabushiki fails to disclose each and every feature recited in independent claim 8, and further, the asserted combination also does not disclose or suggest the specific features of the enteral nutrition product administration device recited in claims 11 and 13.

For at least the reasons explained above, Applicant respectfully submits that the prior art of record fails to disclose or suggest each and every feature recited in the pending claims. Accordingly, Applicant respectfully submits that all claims pending herein define patentable subject matter over the applied references, and respectfully requests that the above rejections be reconsidered and withdrawn.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

January 15, 2009

Date



Stephen P. Burr

Reg. No. 32,970

Nicole J. Buckner

Reg. No. 51,508

SPB/NB/cmb

BURR & BROWN
P.O. Box 7068
Syracuse, NY 13261-7068

Customer No.: 025191
Telephone: (315) 233-8300
Facsimile: (315) 233-8320